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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 10/625,792 | 07/23/2003 | Marc A. Mandro | 1062/D78 | 9009 |
| 2101 | 7590 | 06/09/2005 | EXAMINER | |
| BROMBERG & SUNSTEIN LLP | | | LEE, PATRICK J | |
| 125 SUMMER STREET | | | ART UNIT | |
| BOSTON, MA 02110-1618 | | | PAPER NUMBER | |

2878

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/625,792 | Applicant(s) MANDRO ET AL. | |
| | Examiner Patrick J. Lee | Art Unit 2878 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. This action is in response to amendment filed May 12th, 2005.

Drawings

2. The drawings were received on 8/27/2003. These drawings are acceptable.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,645,177 B1 to Shearn.

Shearn discloses a syringe driver system comprising a syringe (30), syringe body (32), shaft (56), stopper (44), lead screw (54), and plunger (42).

With respect to claims 1, 12, & 17, Shearn discloses a plunger (42) as a plunger rod coupled to stopper (44) as a piston. Plunger (42) on arm (56) discloses a series of marks (58) as an encoded pattern of encoding features. Shearn discloses an optoelectronic detector (74) that includes a light source and a light detector for detecting marks (58). Shearn finally discloses a processor to determine position of the plunger at a near-end-of-infusion point (as a fiducial reference position) and an end of infusion point (see column 8, lines 20-32). While this may not explicitly disclose the displacement, such would have been obvious to one of ordinary skill in the art as it would allow for accurate determination of positioning and accurate determination of the liquid volume in the syringe.

With respect to claims 2-3 & 13, the modified Shearn does not explicitly disclose the use of modulated optical transmission or reflection, but such would have been obvious to one of ordinary skill in the art because this would have allowed for a clear definition of position by providing areas of different light sensing.

With respect to claims 4, 13, & 18, the modified Shearn discloses the optical detector (74) to sense encoding features (58) as regions of modulated optical transmissions through plunger rod (42).

With respect to claims 5 & 15, the modified Shearn illustrates the marks (58) being located at different distances.

With respect to claims 6-9, 16, & 19, the modified Shearn discloses the size of markers (58) being detected by switch (74) to determine the end of infusion point – this

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could disclose information about the reservoir as to its capacity (see column 8, lines 33-43).

With respect to claim 10, the modified Shearn does not explicitly disclose the use of a substantially uniform light source, but such would have been obvious to one of ordinary skill in the art because this would prevent false readings of the sensor from occurring.

With respect to claim 11, the modified Shearn does not explicitly disclose the repetition of encoding features, but such would have been obvious to one of ordinary skill in order to allow for increased range of displacement detection.

With respect to claim 20, the modified Shearn does not explicitly include the step of storing each successive detector array value in each of successive groups, but such would have been obvious to modify the modified Shearn accordingly in order to accurately determine the rate of displacement to calculate a volumetric flow rate out of the syringe.

6. Claims 1, 12, & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0045861 A1 to Tribe.

Tribe discloses a syringe pump comprising syringe (3), plunger (35), plunger actuator (10), optical sensor and encoder disc (20), and control unit (11).

With respect to claims 1, 12, & 17, Tribe discloses plunger (35) coupled to lead screw (8) as a piston with encoding disc (20) as an encoded pattern of encoding features. Tribe discloses the use of optical sensor (20) coupled to encoding disc. As a processor, control unit (11) receives information from optical sensor (20) and adjusts the

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motor accordingly if the plunger (35) reaches the end or there is an obstruction detected to avoid damage to the pump. While Tribe does not explicitly disclose the use of a light source and the determination of displacement, such would be obvious to one of ordinary skill in the art because the light source would make the encoding device much more effective and the determination of displacement is key in order to determine the obstruction of the plunger rod (35) due to the syringe barrel (3).

Response to Arguments

7. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick J. Lee whose telephone number is (571) 272-2440. The examiner can normally be reached on Monday through Friday, 8:00 am to 5:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David P. Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick J. Lee
Examiner
Art Unit 2878

PJL
June 1st, 2005


Stephone B. Allen
Primary Examiner